

REMARKS

Summary of the Office Action

Claims 6, 9-26, and 33 are pending in the application, of which claims 6 and 9-15 are under examination. Claims 16-26 and 33 are withdrawn from consideration as being drawn to a non-elected invention. Claims 6 and 11 have been amended to add the phrase, “wherein the importation competent signal peptide comprises a hydrophobic portion which is derived from the hydrophobic portion of a signal peptide of a protein secreted from cells.” Support for this phrase can be found throughout the application, and specifically on page 10, lines 17-20, which describes the hydrophobic portions of secreted proteins as a common, major motif of the signal peptide of such proteins. Use of sequences from naturally occurring (known) signal peptides is referred to on page 11, lines 5-10, and page 14, lines 5-6, and on page 10, lines 13-20, which refers to the hydrophobic character of the claimed importation competent signal peptides and ties this to the hydrophobic motif of naturally occurring signal peptides.

Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 6, 10, 11, and 13-15 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Applicants would like to thank the Examiner for withdrawing the enablement rejection as it pertains to therapeutic applications and delivering any peptide, polypeptide, or protein into a cell.

The present rejection is allegedly based on the claims being drawn to any importation competent signal peptide. The Examiner argues that undue experimentation would be required to practice the method using the broad scope encompassed by the importation competent signal peptide of the claims.

It is noted that claims 6 and 11 now contain the limitation that the signal peptide comprises a hydrophobic portion which is derived from the hydrophobic portion of a signal peptide of a protein secreted from cells. The Office Action states that, “Thus, the application seeks to claim a method of using any peptide having more than about 10 amino acids and typically, but not limited to, 55-60% are hydrophobic residues to import proteins into cells *in vivo*.” (Page 5). Applicants would like to point out that the claims, as currently amended, do not read on any such peptide, as the claims are now drawn to a “signal peptide [that] comprises a hydrophobic portion which is derived from the hydrophobic portion of a signal peptide of a protein secreted from cells.” Therefore, the signal peptides encompassed by the claims are only those that comprise a hydrophobic portion derived from an existing signal peptide. One of skill in the art would have easily been able to identify such a signal peptide, and select the hydrophobic portion of said peptide. Therefore, it is believed that this amendment is sufficient to overcome the enablement rejection.

Generally speaking, the enablement guidelines found in the MPEP state that to comply with 35 U.S.C. 112, first paragraph, it is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system). Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. Applicants assert that the specification does enable one of skill in the art to make and use signal peptides as currently claimed, since all that would have been required by one of skill in the art is

to make and use the invention is to identify a signal peptide, and then identify its hydrophobic domain. Furthermore, such signal peptides are identified in generally available databases, and those of skill in the art would have known how to obtain them.

The MPEP, section 2164.08, also states that how a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). “Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious.” *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). Applicants assert that one of ordinary skill in the art would have been able to easily identify signal peptides, and their hydrophobic portions, based on the teachings in the specification.

In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated: “[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for ‘preferred’ materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.” Applicants assert that they were the first to disclose that signal peptides can be used to import peptides, polypeptides, or proteins into cells, using hydrophobic portions of signal peptides. Based on *In re Goffe*, as well as the other guidelines discussed above, applicants should be entitled to the scope of signal peptides sought in the claims. Applicants therefore respectfully request withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 6, 10, 11, and 13-15 are rejected under 35 U.S.C. § 112, first paragraph, as lacking sufficient written description. It is noted that the claims now contain the limitation that the signal peptide comprises a hydrophobic portion which is derived from the hydrophobic portion of a signal peptide of a protein secreted from cells. The hydrophobic portions of such signal peptides have structure and properties that allow such hydrophobic portions to function as importation competent signal peptides. It is submitted that this amendment is sufficient to overcome the written description rejection.

In general, however, applicants would like to point out that written description does not require complete structural information. Rather, written description only requires that sufficient written description be provided such that the subject matter of the invention can be distinguished by those of skill in the art. Applicants have provided a clear written description of both the subject matter of the claims and of what is required to fulfill the scope of the claims. In particular, Applicants have provided in the specification sufficient written description of the claimed importation competent signal peptides comprising a hydrophobic portion which is derived from the hydrophobic portion of a signal peptide of a protein secreted from cells. The specification notes that the hydrophobic portion of a signal peptide “is a common, major motif of the signal peptide, and it is often a central part of the signal peptide of protein secreted from cells. A signal peptide is a peptide capable of penetrating through the cell membrane to allow the export of cellular proteins” (page 10, lines 28-31). Applicants also note that signal peptides that mediate passage of proteins through secretory pathway are well known and thus represent a material that those of skill in the art would not misunderstand. This is sufficient for written description. See Amgen v. Hoechst, 314 F.3d 1313, 1332 (Fed. Cir. 2003). Applicants submit

that the specification in combination with the knowledge of those of skill in the art sufficiently describes structural features of importation competent signal peptides and that these structural features are correlated with the function of the ability to penetrating through the cell membrane from outside of the cell to the interior of the cell. This is all that is required to satisfy the written description requirement.

The specification also gives the example of the signal peptide of K-FGF (page 20) as well as other signal peptides, such as those found in the SIGPEP database. As previously discussed, over 500 signal peptides in the SIGPEP database (<http://proline.bic.nus.edu.sg/sigpep/>) include sequences that have the structural characteristics of the claimed importation competent signal peptides. Furthermore, it has since been demonstrated that a variety of signal peptides, including those found in the SIGPEP database, can be used to import a very wide range of cargo. Thus, the specification provides sufficient structural description of the claimed importation competent signal peptides, both in terms of structural features and by reference to known structures that can be used, to show that Applicants were in possession of the claimed subject matter. Therefore, the written description requirement is met.

Applicants submit that the hydrophobic portion of any known signal peptide or any signal peptide of a protein translocated through secretory pathway will have the structure and properties that allow such hydrophobic portions to function as importation competent signal peptides.

Applicants also note that correlation of a function to a known structure in relation to the written description requirement relates to cases where structure is not provided (which is not the case here). That is, the written description “requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003). As noted in *Amgen*,

this principle is an exception to the rule that a purely functional description cannot satisfy the written description requirement. *See id.* Here, Applicants have provided the correlation (as well as a structural description), so there is no need for the art to provide a correlation of structure to function. Nevertheless, the knowledge in the art of the correlation of the structure of signal peptides with the function of passing of proteins having signal peptides through secretory pathway provides extra support for adequate written description of the claimed importation competent signal peptides because the known function of signal peptides is highly relevant to the claimed importation function, i.e. crossing the cell membrane. It is for this additional reason that known signal peptides support written description of the claimed importation competent signal peptides. Therefore, applicants respectfully request withdrawal of this rejection.

In view of the above, the specification provides sufficient description of pending claims 6, 10, 11, and 13-15, and this basis of the written description rejection can be withdrawn.

### CONCLUSION

In view of the above amendments and remarks, reconsideration and allowance of the pending claims is believed to be warranted, and such action is respectfully requested. The Examiner is encouraged to directly contact the undersigned if this might facilitate the prosecution of this application to issuance.

An EFS Web Filing Credit Card Payment Form authorizing payment in the amount of \$510.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(3) and a Request for Extension of Time are being submitted electronically. This amount is believed to be correct;

however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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/Janell T. Cleveland/  
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July 16, 2007  
Date